

(1) *Cattle*—(i) *Amount*. 3 grams per 100 lb. body weight.

(a) *Indications for use*. Control of infections of gastrointestinal roundworms (*Trichostrongylus* spp., *Haemonchus* spp., *Ostertagia* spp., *Nematodirus* spp., *Oesophagostomum radiatum*).

(b) *Limitations*. Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) *Amount*. 5 grams per 100 lb. body weight.

(a) *Indications for use*. Control of severe infections of gastrointestinal roundworms (*Trichostrongylus* spp., *Haemonchus* spp., *Ostertagia* spp., *Nematodirus* spp., *Oesophagostomum radiatum*); control of infections of *Cooperia* spp.

(b) *Limitations*. 5 grams per 100 lb. body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) *Goats*—(i) *Amount*. 3 grams per 100 lb. body weight.

(ii) *Indications for use*. Control of severe infections of gastrointestinal roundworms (*Trichostrongylus* spp., *Haemonchus* spp., *Ostertagia* spp., *Cooperia* spp., *Nematodirus* spp., *Bunostomum* spp., *Strongyloides* spp., *Chabertia* spp., and *Oesophagostomum* spp.).

(iii) *Limitations*. 3 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(3) *Sheep and goats*—(i) *Amount*. 2 grams per 100 lb. body weight.

(ii) *Indications for use*. Control of infections of gastrointestinal roundworms (*Trichostrongylus* spp., *Haemonchus* spp., *Ostertagia* spp., *Cooperia* spp., *Nematodirus* spp., *Bunostomum* spp., *Strongyloides* spp., *Chabertia* spp., and *Oesophagostomum*

spp.); also active against ova and larvae passed by sheep from 3 hours to 3 days after the feed is consumed (good activity against ova and larvae of *T. colubriformis* and *axei*, *Ostertagia* spp., *Nematodirus* spp., *Strongyloides* spp.; less effective against those of *Haemonchus contortus* and *Oesophagostomum* spp.).

(iii) *Limitations*. Use 2 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(4) *For swine*—(i) *Amount*. 45.4–908 grams per ton (0.005–0.1 percent).

(ii) *Indications for use*. Aid in the prevention of infections of large roundworms (genus *Ascaris*).

(iii) *Limitations*. Administer continuously feed containing 0.05–0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005–0.02 percent thiabendazole per ton for 8–14 weeks; do not treat animals within 30 days of slaughter.

(5) *Pheasants*—(i) *Amount*. 454 grams per ton (0.05 percent) continuously for 2 weeks (14 days).

(ii) *Indications for use*. For the treatment of gapeworms (*Syngamus trachea*) in pheasants.

(iii) *Limitations*. Do not use treated pheasants for food for 21 days after last day of treatment. Fertility, hatchability, and other reproductive data are not available on use in breeding animals.

[40 FR 13959, Mar. 27, 1975, as amended at 47 FR 49641, Nov. 2, 1982; 49 FR 29958, July 25, 1984; 51 FR 7400, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987]

§ 558.625 Tylosin.

(a) *Specifications*. Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means. Tylosin, present as the phosphate salt, conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled "Determination of Factor Content in Tylosin by High Performance Liquid Chromatography,"

which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) *Approvals.* Type A medicated article levels of tylosin granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section.

(1) To 000986: 10, 40, 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(2) To 051359: 1, 2, 4, 5, 8, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(3) To 043733: 20 and 40 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(4) [Reserved]

(5) To 017800: 0.4, 0.8, 1, and 8 grams per pound, paragraph (f)(1)(vi)(a) of this section; 10 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(6)—(7) [Reserved]

(8) To 035369: 4 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section; 10 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(9) To 043727: 4 grams per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(10) To 012286: 0.4, 0.8, and 1.6 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20, 40, and 100 grams per pound, paragraphs (f)(1)(i) through (f)(1)(vi) of this section.

(11) [Reserved]

(12) To 021930: 2 grams per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(13) To 035393: 0.4 and 2 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(14) To 016968: 1, 2, 4, 8, and 10 grams per pound, paragraphs (f)(1) (i), (iii), (iv), and (vi) of this section; 20, 25, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(15) [Reserved]

(16) To 049768: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(17) To 021780: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(18) [Reserved]

(19) To 033999: 10 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(20)—(21) [Reserved]

(22) To 026282: 10 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(23)—(24) [Reserved]

(25) To 000069: 4, 8, and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section; 20 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(26)—(30) [Reserved]

(31) To 029341: 5 grams per pound; paragraph (f)(1)(vi)(a) of this section.

(32) [Reserved]

(33) To 034936: 0.8 and 2 grams per pound, paragraph (f)(1)(vi)(a) of this section; 4, 8, and 10 grams per pound, paragraphs (f)(1)(i), (iii), (iv), and (vi) of this section; 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section; 100 grams per pound, paragraphs (f)(1) (i), (ii), (iii), (iv), and (vi) of this section.

(34) To 028260: 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section.

(35) To 039741: 2 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(36)—(37) [Reserved]

(38) To 053740: 1 gram per pound, paragraph (f)(1)(vi)(a) of this section; 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(39) To 050604: 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(40) To 035955: 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(41) [Reserved]

(42) To 010439: 0.4, 0.5, and 2 grams per pound, paragraph (f)(1)(vi) (a) of this section; 5, 10, 20, and 40 grams per pound, paragraph (f)(1)(i) through (vi) of this section.

(43)—(44) [Reserved]

(45) To 017139: 4 and 10 grams per pound, paragraph (f)(1)(vi)(a) of this section.

(46)—(47) [Reserved]
 (48) To 017790: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (49)—(51) [Reserved]
 (52) To 012286: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (53) To 034500: 4 and 10 grams per pound; paragraph (f)(1)(vi)(a) of this section.
 (54) To 046573: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (55)—(56) [Reserved]
 (57) To 028459: 0.4 and 10 grams per pound; paragraph (f)(1)(vi)(a) of this section.
 (58)—(62) [Reserved]
 (63) To 046987: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (64)—(65) [Reserved]
 (66) To 024174: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (67) To 027190: 2 grams per pound; paragraph (f)(1)(vi)(a) of this section.
 (68) To 017473: 10 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (69)—(71) [Reserved]
 (72) To 012190: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (73) To 035098: 0.33 and 0.67 gram per pound, paragraph (f)(1)(vi)(a) of this section; 0.8, 1, 2, and 10 grams per pound, paragraphs (f)(1) (i) and (vi) (a), (b) and (d) of this section; 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (74)—(75) [Reserved]
 (76) To 021502: 10 grams per pound; paragraph (f)(1)(vi)(a) of this section.
 (77) To 050639: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (78) To 050972: 0.36, 0.4, 0.72, and 0.8 gram per pound, paragraph (f)(1)(vi)(a) of this section; 1 gram per pound, paragraphs (f)(1)(vi) (a), (b), and (d) of this section.
 (79) To 047427: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (80) To 049685: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(81)—(82) [Reserved]
 (83) To 046573: 5-, 10-, 20-, and 40-grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (84) To 043734: 4, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (85) To 047126: 10, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.
 (86)—(88) [Reserved]
 (89) To 053389: 5, 10, 20, and 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section.
 (c)—(d) [Reserved]
 (e) *Related tolerances.* See § 556.740 of this chapter.
 (f) *Conditions of use.* (1) It is used in animal feeds as follows:
 (i) *For beef cattle—(a) Amount per ton.* 8–10 grams.
 (b) *Indications for use.* For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Corynebacterium pyogenes*.
 (c) *Limitations.* As tylosin phosphate; each animal must receive not more than 90 milligrams per day and not less than 60 milligrams per day; feed continuously as sole ration.
 (ii) *Broiler chickens—(a) Amount per ton.* Tylosin, 800–1000 grams.
 (b) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum*.
 (c) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24–48 hours at 3 to 5 weeks of age.
 (iii) *Chickens—(a) Amount per ton.* Tylosin, 4–50 grams.
 (1) *Indications for use.* For increased rate of weight gain and improved feed efficiency.
 (2) *Limitations.* As tylosin phosphate.
 (iv) *Laying chickens—(a) Amount per ton.* Tylosin, 20–50 grams.
 (b) *Indications for use.* For improved feed efficiency.
 (c) *Limitations.* As tylosin phosphate.
 (v) *Replacement chickens—(a) Amount per ton.* Tylosin, 1,000 grams.
 (b) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum*.

(c) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24 to 48 hours at 3 to 5 weeks of age.

(vi) *Swine*—(a) *Amount per ton.* Tylosin, 10-100 grams.

(1) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* As tylosin phosphate; continuous use as follows: *Grams per ton:* 20-100, prestarter or starter; 20-40, grower; 10-20, finisher.

(b) *Amount per ton.* Tylosin, 40-100 grams.

(1) *Indications for use.* Prevention of swine dysentery (vibrionic).

(2) *Limitations.* Use 100 grams per ton for at least 3 weeks followed by 40 grams per ton until market weight; as tylosin phosphate.

(c) *Amount per ton.* Tylosin, 40-100 grams.

(1) *Indications for use.* Treatment and control of swine dysentery (vibrionic).

(2) *Limitations.* Administer in feed as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 gram per gallon in drinking water for 3-10 days, 40-100 grams per ton in feed for 2-6 weeks.

(d) *Amount per ton.* Tylosin, 100 grams.

(1) *Indications for use.* Maintaining weight gains and feed efficiency in presence of atrophic rhinitis.

(2) *Limitations.* As tylosin phosphate.

(2) Tylosin may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Hygromycin B as in § 558.274.

(ii) Melengestrol acetate alone or in combination with certain ionophores in accordance with § 558.342.

(iii) [Reserved]

(iv) Monensin in accordance with § 558.355.

(v) Pyrantel tartrate in accordance with § 558.485.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.625, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 558.630 Tylosin and sulfamethazine.

(a) [Reserved]

(b) *Approvals.* Type A medicated article levels, a combination of equal amounts of tylosin and sulfamethazine, granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section.

(1) To 000986: 40 grams per pound each, paragraph (f)(2)(i).

(2) To 000986: 10 grams per pound each, paragraph (f)(2)(i).

(3) To 012286, 034500: 10 grams per pound each, paragraph (f)(2)(ii) of this section.

(4) To 021780: 2 grams per pound each, paragraph (f)(2)(ii) of this section.

(5) To 017800: 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(6) To 017139: 4, 10, or 20 grams per pound each, paragraph (f)(2)(ii) of this section.

(7) To 021930: 2 grams per pound each, paragraph (f)(2)(i) of this section; 5, 10, 20, or 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(8) To 012286, 026186: 5 or 10 grams per pound each, paragraph (f)(2)(ii) of this section.

(9) [Reserved]

(10) To 010439, 011749, 012190, 012286, 016968, 017473, 017519, 017790, 021780, 024174, 030841, 034936, 035098, 043727, 043733, 046573, 046987, 050568, 050639, and 051359 053389: 5, 10, 20, or 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(c)—(d) [Reserved]

(e) *Related tolerances.* See §§ 556.670 and 556.740 of this chapter.

(f) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount per ton.* Tylosin, 100 grams plus sulfamethazine, 100 grams.

(2) *Indications for use.* (i) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*P. multocida* and/or *C. pyogenes*); for reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E Streptococci. Only